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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/895,975 | 06/29/2001 | Mark R. Schmitt | AM100341 | 9267 |

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/13/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---|------------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/895,975 Examiner Tamthom N. Truong | SCHMITT ET AL. Art Unit 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 October 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-94 is/are rejected.

7) Claim(s) 95 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of the species of Example 133 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-95 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-21, 23-43, 45-65, and 67-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:
 - a. Claims 1, 23 and 45 appear as substantial duplicates of each other because they all recite the method of "inhibiting the growth of cancerous, tumorous cells" by administering "a substituted triazolopyrimidine derivative". Although claims 23 and 45 recite some functional language, said language does not have patentable weight because it does not contribute to a structural change in the triazolopyrimidine derivative.

b. Since claims 1, 23 and 45 are substantial duplicates, their dependent claims are also substantial duplicates as well. That is, claims 2-22, and 67 have the same scope with claims 23-44, and 68, which in turn have the same scope with claims 45-66, and 69.

c. Claims 2, 24, 46, 70-72 and 75 recite several instances of Broad/Narrow Range, such as the followings:

- i. Broad limitation of “optionally substituted alkyl of 1-12 carbon atoms” vs. narrow limitation of “haloalkyl of 1-10 carbon atoms” (e.g. see the definitions of R^a and R^b);
- ii. Broad limitation of “heterocyclyl” vs. narrow limitation of “optionally substituted cycloalkyl of 3 to 8 carbon atoms in which one –CH₂- may also be replaced by –O-, -S-, or –NR’...” (e.g., see the definitions of R¹, R^a, R^b, R^c, and R^d);
- iii. Broad limitation of “heterocyclyl” vs. narrow limitation of “3- to 6-membered heterocyclyl ring, optionally ortho-fused...” (e.g., see the definition of R^a);
- iv. Broad limitation of “aralkyloxy” vs. narrow limitation of “benzyloxy” (e.g., see the definition of R³);

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in

Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

d. Claims 4, 26, 48, and 77 lack antecedent basis because said claims recite (R) or (S) isomer, which is not recited in the claims they depend on.

e. Claims 3-21, 25-43, 47-65, and 76-94 are rejected because they carry over limitations of claims 2, 24, 46, and 75.

f. Claims 7, 11, 29, 33, 51, 55, 80, and 84 are indefinite because they recite the broad limitation of "optionally substituted alkyl..." followed by the narrow limitation of "-CF₃". Thus, the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

g. Claims 17-21, 39-43, 61-65, and 90-94 are indefinite because they seem to recite an incomplete limitation of "wherein R^aR^b are optionally taken together with the nitrogen to which each is attached;" (?) It is not understood what moiety is described by said phrase.

h. Claims 20, 21, 42, 43, 64, 65, 93, and 94 are indefinite for reciting the broad limitation of "-NR^aR^b" followed by the narrow limitations of individual functional groups

and rings such as: -N(C₂H₅)₂, -N-CH-(CH₃)₂, -(N-piperidinyl)-CH₃, etc. Thus, the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

- i. Claims 70, 71, and 72 are substantial duplicates because they recite pharmaceutical compositions with different intended uses. However, intended uses do not have patentable weight.
- j. Claims 73 and 74 recite “a method for the treatment or prevention of multiple drug resistance (MDR)...” which is unclear as to the disorders being treated. Also, it is not clear what resists what.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6-8, 11, 12, 15, 23-25, 28-30, 33, 34, 37, 45-47, 50-52, 55, 56, 59 and 67-72 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Suiko et. al.** (Agric. Biol. Chem., 41(10), 1977, pp. 2047-2053). On page 2051, Suiko et. al. disclose pseudopurines with antitumor activity in Table IV. Said pseudopurines are embraced by the claimed triazolopyrimidine of formula (I) with the following substituents:

- v. R^1 is alkyl or hydroxy;
- vi. R^2 is H, halogen, or alkoxy carbonyl of 2 carbon atom;
- vii. R^3 is hydrogen or alkyl; and R^4 is hydrogen.

Said compounds can inhibit the growth of E-cells. Thus, the method for inhibiting cancerous tumorous cells is embraced, and the mechanism of action in claims 23 and 45 are inherently embraced. Also, pharmaceutical compositions and methods of treating particular cancers in claims 67-72 are inherently anticipated as well.

Claim Objections

3. Claim 95 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The references of record do not teach species recited

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong

January 10, 2003



RICHARD L. MAYNARD
PRIMARY EXAMINER
ART UNIT 1624